

September 17, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.60

Subject: Biological Products Returned to Licensed or Permitted Establishments

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum provides guidance to licensees and permittees on procedures for handling biological products returned to licensed or permitted establishments to ensure compliance with 9 CFR 114.11.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.60, dated March 29, 1984.

III. GENERAL

CVB discourages licensees and permittees from accepting the return of veterinary biological products to the licensed or permitted establishment for resale or redistribution. Once a product has left the licensed or permitted establishment, it is often difficult to determine if it has been maintained under proper conditions of storage and handling in compliance with 9 CFR 114.11. To ensure that all products that are distributed meet APHIS standards, use the following procedures to handle returned products.

IV. PROCEDURES

A. Identify and Separate Returned Products

Properly identify all products returned to the licensed or permitted establishment and keep them separate from other products.

B. Resale and Redistribution

Licensees and Permittees may ship a returned veterinary biological product for resale and redistribution only when adequate documentation is available to ensure that the entire

quantity of product returned has been handled and stored in a uniform, acceptable manner. Preferably, firms should support such documentation by a satisfactory retest of the product for potency.

C. Product Not Eligible for Release

Destroy all returned products which do not meet these guidelines according to Veterinary Services Memorandum No. 800.56 since they are not eligible for release for resale and redistribution.

/s/ Thomas E. Walton for

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Deputy Administrator
Veterinary Services